68-9-3. Automated drug delivery system for distribution of drugs. (a) For purposes of this regulation "automated drug delivery system" shall ~~means~~ mean a robotic, mechanical, or computerized device that is used for supplying drugs for administration in ~~a~~

(1) A medical care facility, as defined in K.S.A. 65-425;

(2) an institutional drug room, as defined in K.S.A. 65-1626 and amendments thereto;

(3) or a long-term care facility, which shall ~~means~~ mean a nursing facility as defined in K.S.A. 39-923 and amendments thereto.

(b) A managing pharmacy located in Kansas shall provide the board with prior written notice of the installation of an automated drug delivery system on a form provided by the board or upon the removal of any automated drug delivery system and ensure that all necessary licenses, registrations, and authorizations, including a drug enforcement administration permit for supplying controlled substances, have been obtained ~~prior to engaging the use~~ before using or stocking ~~of~~ an automated drug delivery system.

(c) The pharmacist-in-charge of the managing pharmacy shall be responsible for the following:

(1) Maintaining a record of each transaction or operation;

(2) controlling access to the automated drug delivery system; ~~and~~

(3) maintaining policies and procedures for the following:

(A) Operating the automated drug delivery system;

(B) obtaining preapproval, ~~and~~ training ~~of~~ personnel who are authorized to remove any drug, and ~~maintain~~ maintaining, at the location of the automated drug delivery system, a list of those individuals;

(C) maintaining patient services whenever the automated drug delivery system is not operating; and

(D) defining a procedure for a pharmacist to grant access to the drugs in the automated drug delivery system or to deny access to the drugs in the automated drug delivery system;

(4) securing the automated drug delivery system;

(5) ~~assuring~~ ensuring that ~~a~~ each patient receives the pharmacy services necessary for appropriate pharmaceutical care;

(6) ~~assuring~~ ensuring that the automated drug delivery system maintains the integrity of the information in the system and protects patient confidentiality;

(7) establishing a procedure for stocking and restocking the automated drug delivery system;

(8) ensuring compliance with all requirements for packaging and labeling medications pursuant to K.A.R. 68-7-15 and K.A.R. 68-7-16 or package in a manufacturer's sealed original package or in repackaged containers;

(9) ensuring preventive maintenance and sanitation of the automated drug delivery system; ~~and~~

(10) ensuring that the automated drug delivery system has a mechanism for securing and accounting for drugs removed from and subsequently returned to the automated drug delivery system;

(11) ensuring that there is a policy in place for securing and accounting for wasted or discarded drugs;

(12) ensuring preventive maintenance and sanitation of the automated drug delivery system;

(13) ensuring that inspections are conducted and documented at least monthly to ensure accuracy of contents; and

(14) ensuring the accurate stocking and restocking of each automated drug delivery system by approving and implementing an operational policy that limits the personnel responsible for the loading and unloading of the automated drug delivery system to a Kansas-licensed pharmacist or to either of the following, each of whom shall be under the pharmacist's supervision:

(A) ~~a~~ A Kansas-registered pharmacy intern; or

(B) a Kansas-registered pharmacy technician.

(d) A pharmacist shall perform prospective drug use review and approve each medication order ~~prior to~~ before the administration of ~~a~~ each drug, except an override or a physician-controlled medication.

(e) A pharmacist shall perform a retrospective drug use review for ~~an~~ each override medication.

(f) The pharmacist-in-charge shall consult with the pharmacy and therapeutics committee or an equivalent committee in establishing the criteria and process for determining which drugs qualify as an override medication.

(g) The managing pharmacy shall review all emergency medication orders and any discrepancies or transaction reports within 72 hours.

(h) ~~A~~ Any pharmacy utilizing an automated drug delivery system may distribute patient-specific drugs without verifying each individual drug selected or packaged by the automated drug delivery system if both of the following conditions are met:

(1) The initial medication order has been reviewed and approved by a pharmacist ~~and~~.

(2) the drug is distributed for subsequent administration by a health care professional permitted by Kansas law to administer drugs.

(i) The pharmacist-in-charge shall be responsible for establishing a quality assurance program for the automated drug delivery system. ~~The~~ This program shall provide for the following:

(1) Review of override medication utilization;

(2) investigation of any medication error related to drugs distributed or packaged by the automated drug delivery system;

(3) review of any discrepancy or transaction reports and identification of patterns of inappropriate use or access of the automated drug delivery system;

(4) review of the operation of the automated drug delivery system;

(5) integration of the automated drug delivery system quality assurance program with the overall continuous quality improvement program of the pharmacy ~~or risk management program of a hospital~~; and

(6) assurance that all individuals working with the automated drug delivery system receive appropriate training on the operation of the automated drug delivery system and procedures for maintaining pharmacy services when the automated drug delivery system is not in operation.

(j) The pharmacist-in-charge shall maintain for at least five years the following records related to the automated drug delivery system in a readily retrievable manner:

(1) Transaction records for all non-controlled drugs or devices distributed by the automated drug delivery system;

(2) transaction records from the automated drug delivery system for all controlled substances distributed; and

(3) any report or analysis generated as part of the quality ~~improvement~~ assurance program required by ~~paragraph~~ subsection (i) ~~of this rule~~.

(k) A pharmacist shall conduct and document a daily audit of the drugs placed or to be placed into an automated drug delivery system by a pharmacy intern or pharmacy technician, which ~~audit~~ may include random sampling.

(l) A bar code verification, electronic verification, or similar verification process shall be utilized to ~~assure~~ ensure correct selection of drugs placed or to be placed into ~~an~~ each automated drug delivery system. The utilization of a bar code, electronic verification or similar verification

process shall require an initial quality assurance validation, followed by a quarterly assurance review by a pharmacist. ~~When~~ If a bar code verification, electronic verification, or similar verification process is utilized as specified in this subsection, stocking and restocking functions may be performed by a pharmacy technician, pharmacy intern, or ~~a~~ registered nurse trained and authorized by the pharmacist-in-charge.

(m) The pharmacist performing the quality assurance review shall maintain a record of the quality assurance process that occurred and the pharmacist approval of the drug stocking, restocking, or verification process.

(n) If any drug ~~that~~ has been removed from the automated drug delivery system, that drug shall not be replaced into the automated drug delivery system unless either of the following conditions is met:

(1) The drug's purity, packaging, and labeling have been examined according to policies and procedures established by the pharmacist-in-charge to determine that the reuse of the drug is appropriate ~~or~~.

(2) The drug is one of the specific drugs, ~~such as~~ including multidose vials, that have been exempted by the pharmacy and therapeutics committee or an equivalent committee.

(Authorized by K.S.A. 65-1630; implementing K.S.A. 2013 Supp. 65-1626 and K.S.A. 65-1648; effective P-_____.)